

IPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stefan M. Pulst

Application No.: 10/750,323

Group Art Unit: 1634

Filed: December 30, 2003

Examiner: Not assigned yet

Confirmation No.: 4927

Title: NUCLEIC ACID ENCODING SPINOCEREBELLAR ATAXIA-2 AND
PRODUCTS RELATED THERETO

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
9-13-04	<i>David M. Myers</i>
Date	Signature
<i>David M. Myers</i>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references were entered in prior applications, U.S. Application No. 08/727,084 and U.S. Application No. 09/083,268 to which priority under 35 U.S.C. 120 is claimed. The earlier applications contain copies of the cited references.
- ☒ The listed references (AM, AN, AY3, AT5, AU5, AX5 and AY5) were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

_____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

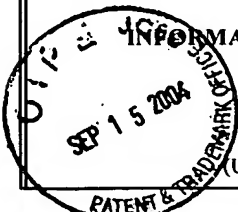
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

Deirdre E. Sanders
Deirdre E. Sanders
Registration No.: 42,122
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

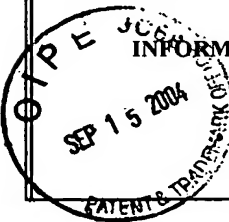
Concord, MA 01742-9133

Dated: September 13, 2004

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3350.1000-005		APPLICATION NO. 10/750,323	
 <p>September 13, 2004</p> <p>(Use several sheets if necessary)</p>		FIRST NAMED INVENTOR Stefan M. Pulst		FILING DATE December 30, 2003	
		EXAMINER Not yet assigned		CONFIRMATION NO. 4927	

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	5,552,282	09/03/1996	Caskey, <i>et al.</i>
	AB	5,650,277	07/22/1997	Giese, <i>et al.</i>
	AC	5,650,277	07/22/1997	Navot, <i>et al.</i>
	AD	5,741,645	04/21/1998	Orr, <i>et al.</i>
	AE	5,474,796	12/12/1995	Brennan
	AI	6,251,589 B1	06/26/2001	Tsuji, <i>et al.</i>
	AG	5,155,218	10/13/1992	Weinshank, <i>et al.</i>
	AH	5,885,834	03/23/1999	Epstein
	AI			
	AJ			
	AK			
	AA2			
	AB2			
	AC2			
	AD2			
	AE2			
	AF2			
	AG2			
	AH2			
	AI2			
	AJ2			
	AK2			
	AA			
	AB3			
	AC3			

EXAMINER	DATE CONSIDERED
----------	-----------------

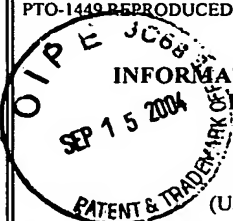
PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3350.1000-005	APPLICATION NO. 10/750,323	
 INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 13, 2004 (Use several sheets if necessary)		FIRST NAMED INVENTOR Stefan M. Pulst		FILING DATE December 30, 2003
		EXAMINER Not yet assigned	CONFIRMATION NO. 4927	GROUP 1634

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION	
					YES	NO
	AL	WO 97/18224	05/22/1997	Human Genome Sciences, Inc.		
	AM	WO 95/01437	01/12/1995	Regents of The University of Minnesota		
	AN	WO 97/17445	05/15/1997	Centre National De La Recherche Scientifique		
	AO					
	AP					
	AQ					
	AL2					
	AM2					
	AN2					
	AO2					
	AP2					
	AQ2					
	AL3					
	AM3					
	AN3					
	AO3					
	AP3					
	AQ3					
	AL4					
	AM4					
	AN4					
	AO4					
	AP4					
	AQ4					

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED  INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 13, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3350.1000-005	APPLICATION NO. 10/750,323	
	FIRST NAMED INVENTOR Stefan M. Pulst		FILING DATE December 30, 2003
	EXAMINER Not yet assigned	CONFIRMATION NO. 4927	GROUP 1634

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Choudhry, S., <i>et al.</i> , "CAG Repeat Instability at SCA2 Locus: Anchoring CAA Interruptions and Linked Single Nucleotide Polymorphisms," <i>Human Molecular Genetics</i> , 10:2437-3446 (2001).
AS	Mizushima, K., <i>et al.</i> , "Analysis of Spinocerebellar Ataxia Type 2 Gene and Haplotype Analysis: (CGG) ₁ , ₂ Polymorphism and Contribution to Founder Effect," <i>Journal of Medical Genetics</i> , 36:112-114 (1999).
AT	Sahba, S., <i>et al.</i> , "Genomic Structure of the Human Gene for Spinocerebellar Ataxia Type 2 (SCA2) on Chromosome 12q24.1," <i>Genomics</i> , 47:359-364 (1998).
AU	Sanpei, <i>et al.</i> , "Direct Detection of Expanded (CAG/CTG) Repeats in the Myotonin-protein Kinase Genes of Myotonic Dystrophy Patients Using a High-Stringency Hybridization Method," <i>Biochem. Biophys. Res. Commun.</i> , 212(2), 341-346 (July 17, 1995).
AV	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, Blast 2 Sequence Results of gi 4506794 and gi 12382830 [online]. Bethesda, MD [retrieved on November 26, 2001]. Retrieved from Internet:<URL: http://www.ncbi.nlm.nih.gov/blast/bl2seq/wblast2.cgi >, 2 pages.
AW	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, Blast 2 Sequence results of gi 4506794 and gi 12382831 [online]. Bethesda, MD [retrieved on November 26, 2001]. Retrieved from the Internet:,URL: http://www.ncbi.nlm.nih.gov/blast/bl2seq/wblast2.cgi >, 2 pages.
AX	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, Blast 2 Sequence results of gi 4506794 and gi 12382832 [online]. Bethesda, MD [retrieved on November 26, 2001]. Retrieved from the Internet:,URL: http://www.ncbi.nlm.nih.gov/blast/bl2seq/wblast2.cgi >, 2 pages.
AY	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, Blast 2 Sequence results of gi 4506794 and gi 12382833 [online]. Bethesda, MD [retrieved on November 26, 2001]. Retrieved from the Internet:,URL: http://www.ncbi.nlm.nih.gov/blast/bl2seq/wblast2.cgi >, 2 pages.
AZ	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, Blast 2 Sequence results of gi 4506794 and gi 12382834 [online]. Bethesda, MD [retrieved on November 26, 2001]. Retrieved from the Internet:,URL: http://www.ncbi.nlm.nih.gov/blast/bl2seq/wblast2.cgi >, 2 pages.

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 13, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3350.1000-005		APPLICATION NO. 10/750,323	
	FIRST NAMED INVENTOR Stefan M. Pulst		FILING DATE December 30, 2003	
	EXAMINER Not yet assigned	CONFIRMATION NO. 4927	GROUP 1634	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR2	National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health, Blast 2 Sequence results of gi 4506794 and gi 12382835 [online]. Bethesda, MD [retrieved on November 26, 2001]. Retrieved from the Internet; URL: http://www.ncbi.nlm.nih.gov/blast/bl2seq/wblast2.cgi , 2 pages.
AS2	GenBank Accession Number Y08262, Imbert, <i>et al.</i> , Sept. 1996.
AT2	GenBank Accession Number T78912, Lutz, <i>et al.</i> , May 1997.
AU2	GenBank Accession Number A62706, Tora, <i>et al.</i> , May 1997.
AV2	GenBank Accession Number AA476524, Hillier, <i>et al.</i> , Jan. 1995.
AW2	GenBank Accession Number L27350, Ambrose, <i>et al.</i> , 1994.
AX2	GenBank Accession Number U70323, Pulst, <i>et al.</i> , Sept. 1996.
AY2	GenBank Accession Number AF041472, Nechiporuk, <i>et al.</i> , Jan. 1998.
AZ2	"PCT Kits," from 1992/1993 Biotechnology Catalog, Perin Elmer, pgs 11-12, 1992.
AR3	Filla, <i>et al.</i> , "Has Spinocerebellar Ataxia Type 2 a Distinct Phenotype?," <i>Neurology</i> , 45:793-796 (April 1995).
AS3	Banfi, <i>et al.</i> , "Identification and Characterization of the Gene Causing Type 1 Spinocerebellar Ataxia," <i>Nature Genet.</i> , 7:513-519 (1994).
AT3	Belal, <i>et al.</i> , "Clinical and Genetic Analysis of a Tunisian Family with Autosomal Dominant Cerebellar Ataxia Type 1 Linked to the SCA2 Locus," <i>Neurology</i> , 44:1423-1426 (1994).
AU3	Brook, "Repeat of the Triplet Repeat," <i>Nature Genet.</i> , 3:279-281 (1993).
AV3	Brunner, <i>et al.</i> , "Brief Report: Reverse Mutation in Myotonic Dystrophy," <i>New Eng. J. Med.</i> , 328:476-480 (1993).
AW3	Filla, <i>et al.</i> , "Prevalence of Hereditary Ataxias and Spastic Paraplegias in Molise, a Region of Italy," <i>J. Neurol.</i> 239:351-353 (1992).

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 13, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3350.1000-005		APPLICATION NO. 10/750,323	
	FIRST NAMED INVENTOR Stefan M. Pulst		FILING DATE December 30, 2003	
	EXAMINER Not yet assigned	CONFIRMATION NO. 4927	GROUP 1634	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AX3	Gispert, <i>et al.</i> , "Chromosomal Assignment of the Second Locus for Autosomal Dominant Cerebellar Ataxia (SCA2) to Chromosome 12q23-24.1," <i>Nature Genet.</i> 4:294-299 (1993).
AY3	Imbert, "Cloning of the Gene for Spinocerebellar Ataxia 2 Reveals a Locus with High Sensitivity to Expanded CAG/glutamine Repeats," <i>Nature Genet.</i> , 14:285-291(1996).
AZ3	Ioannou, <i>et al.</i> , A New Bacteriophage P1-derived Vector for the Propagation of Large Human DNA Fragments," <i>Nature Genet.</i> , 6:84-89 (1994).
AR4	Kawaguchi, <i>et al.</i> , "CAG Expansions in a Novel Gene for Machado-Joseph Disease at Chromosome 14q32.1," <i>Nature Genet.</i> , 8:221-227 (1994).
AS4	Koide, <i>et al.</i> , "Unstable Expansion of CAG Repeat in Hereditary Dentatorubralpallidoluysian Atrophy (DRPLA)," <i>Nature Genet.</i> , 6:9-13 (1994).
AT4	Kremer, <i>et al.</i> , "Mapping of DNA Instability at the Fragile X to a Trinucleotide Repeats Sequence p(CCG)n," <i>Science</i> , 252:1711-1714 (1991).
AU4	Lopes-Cendes, <i>et al.</i> , "Confirmation of the SCA-2 locus as an Alternative Locus for Dominantly Inherited Spinocerebellar Ataxias and Refinement of the Candidate Region," <i>Am. J. Hum. Genet.</i> , 54:774-781 (1994).
AV4	MacDonald, <i>et al.</i> , "A Novel Gene Containing a Trinucleotide Repeat that is Expanded and Unstable on Huntington's Disease Chromosomes," <i>Cell</i> , 72:971-983 (1993).
AW4	Mahadevan, <i>et al.</i> , "Myotonic Dystrophy Mutation: An Unstable CTG Repeat in the 3' Untranslated Region of the Gene," <i>Science</i> , 255:1253-1255 (1992).
AX4	Mandel, "Questions of Expansion," <i>Nature Genet.</i> , 4:8-9 (1993).
AY4	Nagafuchi, <i>et al.</i> , "Dentatorubral and Pallidoluysian Atrophy Expansion of an Unstable CAG Trinucleotide on Chromosome 12p," <i>Nature Genet.</i> , 6:4-18 (1994).
AZ4	Orr, <i>et al.</i> , "Expansion of an Unstable Trinucleotide CAG Repeat in Spinocerebellar Ataxia Type 1," <i>Nature Genet.</i> , 4:221-226 (1993).
AR5	Polo, <i>et al.</i> , "Hereditary Ataxias and Paraplegias in Cantabria, Spain," <i>Brain</i> , 114:855-866 (1991).

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION September 13, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3350.1000-005		APPLICATION NO. 10/750,323	
	FIRST NAMED INVENTOR Stefan M. Pulst		FILING DATE December 30, 2003	
	EXAMINER Not yet assigned		CONFIRMATION NO. 4927	GROUP 1634

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AS5	Pulst, <i>et al.</i> , "Anticipation in Spinocerebellar Ataxia Type 2," <i>Nature Genet.</i> , 5:8-10 (1993).	
AT5	Pulst, <i>et al.</i> , "Genetic and Physical Map of the Spinocerebellar Ataxia 2 (SCA2) Region on Human Chromosome 12," <i>Neurology</i> , 45:A422 (1995).	
AU5	Pulst, <i>et al.</i> , "Moderate Expansion of a Normally Biallelic Trinucleotide Repeat in Spinocerebellar Ataxia Type 2," <i>Nature Genet.</i> , 14:269-276 (1996).	
AV5	Ranum, <i>et al.</i> , "Spinocerebellar Ataxia Type 5 in a Family Descended from the Grandparents of President Lincoln Maps to Chromosome 11," <i>Nature Genet.</i> 8:280-284 (1994).	
AW5	Rubensztein, <i>et al.</i> , "Phenotypic Characterization of Individuals with 30-40 CAG Repeats in the Huntington Disease (HD) Gene Reveals HD Cases with 36 Repeats and Apparently Normal Elderly Individuals with 36-39 Repeats," <i>Am. J. Hum. Genet.</i> , 59:16-22 (1996).	
AX5	Sanpei, <i>et al.</i> , "Identification of the Spinocerebellar Ataxia Type 2 Gene Using a Direct Identification of Repeat Expansion and Cloning Technique, DIRECT," <i>Nature Genet.</i> , 14:277-284 (1996).	
AY5	Stevanin, <i>et al.</i> , "Screening for Proteins with Polyglutamine Expansions in Autosomal Dominant Cerebellar Ataxias," <i>Hum. Mol. Gen.</i> , 5:1887-1892 (1996).	
AZ5	Takiyama, <i>et al.</i> , "The Gene for Machado-Joseph Disease Maps to Human Chromosome 14q," <i>Nature Genet.</i> , 4:300-304 (1993).	
AR6	The WashU-Merck EST Project, "Soares Parathyroid Tumor NbHPA Homo Sapiens cDNA Clone," Accession No. W39162, May 15, 1996.	
AS6	Trottier, <i>et al.</i> , "Polyglutamine Expansions as a Pathological Epitope in Huntington's Disease and Four Dominant Cerebellar Ataxias," <i>Letters to Nature</i> , 378:403-406 (1995).	

EXAMINER	DATE CONSIDERED
----------	-----------------